

distinctions between the claims and the applied art. Examiner Basichas indicated he would further consider such discussed distinctions when formally presented in a filed response.

Addressing now the above-noted rejections of Claims 6-13, those rejections are traversed by the present response.

The applicants of the present invention have recognized that a problem exists in the current art in that until the present invention it was not possible to have a bag in which a ready to use solution could be reconstituted from a sterile product such that the sterile product could be reconstituted directly into the bag still under sterile conditions to form solutions that could then be taken out from the bag as a whole all at one time or as partial (e.g., single doses) portions of the total volume of the reconstituted solution.

As discussed in the present specification, a bag in which a sterile product is formed and which must be completely filled with a solvent to form a solution has been realized. However, the drawback with that type of device is that since the bag must be completely filled with the solvent a complete solution of the powder cannot be attained by simply shaking the bag, and therefore the bag must require additional devices for creating turbulence within the bag. Further, since the bag is always completely filled, the bag must always start out with the same amount of soluble sterile product.<sup>1</sup>

Claims 6-13 provide an improved bag such that the volume of the bag is larger than the volume of the reconstituted ready to use solution after the reconstitution. That is, in the bag of the claims after a solvent is introduced into the bag and mixes with the soluble sterile product, the reconstituted solution only partially fills a capacity of the bag. That allows the bag to be easily shaken to achieve a proper solution. That also allows different quantities of soluble sterile product to be initially placed in the bag.

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<sup>1</sup>See the Substitute Specification at page 3, line 10 et seq.

To make the explanation of the claimed invention simplified, as a concrete example imagine that a sterile product in powder form to be stored within the bag is a crystalline antibiotic to be used for reconstituting injectable solutions in which the concentration of the antibiotic material must be exactly controlled at a specified value.

Before the claimed invention was made and exploited, it was common practice to use glass bottles containing single doses of antibiotic that was dissolved directly within the bottles by feeding water into the bottles. The thereby formed single dose solutions were then drawn into syringes to be injected into patients. Such an operation is demanding and costly, particularly at hospitals where such an operation has to be repeated a large number of times everyday.

It is also not believed currently possible to prepare solutions of antibiotics in bags in suitable plants to then dispatch them to hospitals, because such solutions remain unaltered for a very short time.

- The outstanding rejection is correct in stating that each of the applied art to Slater, Scharf, and Beigler disclose hermetically sealed bags for preserving and transporting a predetermined amount of a soluble sterile product in powder form and for reconstituting in a bag a ready to use solution having a predetermined concentration of the sterile product.

- However, each of the three references to Slater, Scharf, and Beigler have a common feature that has rendered the disclosed bags impractical for actual usage. That common feature is that in each of the bags, the bags must be completely filled with solvent. That deficiency in each of the bags in Slater, Scharf, and Beigler is believed to not be properly and fully considered in the outstanding rejection.

The outstanding rejection recognizes that none of Slater, Scharf, nor Beigler state that a solvent should be added to a volume less than a capacity of the bag. To overcome that

recognized deficiency in each of the applied art to Slater, Scharf, and Beigler, the outstanding Office Action states:

Adding less than the full capacity of the bag in order to allow for room to shake is well within the knowledge and ability to one of ordinary skill in the art; it is a simple matter of common sense. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided for only filling the bag with less than the capacity of the bag or 1.5 to 2 times the volume of the ready to use solution into the inventions of Slater, Scharf, and Beigler in order to provide room to shake the contents of the bag.<sup>2</sup>

Further, the outstanding Office Action states:

As stated by applicants, it is not that the bag and its contents are new, but that filling the bag only partially to allow room for shaking is. This is not patentable. As discussed in the above rejection, it is not only obvious to one of ordinary skill in the art, but simple, common sense.<sup>3</sup>

The above-noted grounds for maintaining the outstanding rejection is traversed on the following aspects. First, the feature of allowing the bag to be easily shaken to achieve a proper solution as noted above is only one of the benefits achieved by the claimed invention. Another benefit is that the structure of the claimed invention allows different quantities of soluble, sterile product to be initially placed in the bag. In the devices in the cited art, as the bags are to be completely filled, they must always have the same initial amount of sterile product therein to achieve a desired concentration. In the claimed invention, since the bag is only partially filled, a different amount of sterile product can be initially placed in the bag.

Moreover, in each of the cited art if the bag was only partially filled with a fluid, an improper concentration of the sterile product would result. That is, in each of the devices of Slater, Scharf, and Beigler a quantity of the sterile products provided in the bag initially is

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<sup>2</sup>Office Action of December 13, 2002, page 3, last seven lines.

<sup>3</sup>Office Action of December 13, 2002, page 4, pre-numbered paragraph 5.

specifically selected so that when the bags are fully filled with a solvent an appropriate concentration is realized. By only partially filling the bags in Slater, Scharf, and Beigler, that appropriate concentration would not be achieved. Thus, the devices in Slater, Scharf, and Beigler would actually be inoperative if they were not completely filled with a solvent.

Further along those lines, what the outstanding Office Action disregards as obvious or "simple common sense" is clearly not obvious or simple common sense as it is directly contrary to what is actually taught in the applied references. That is, each of the applied references, as discussed in further detail below, discloses completely filling a bag. As that is the case, it is unclear how the Office Action can indicate that a directly contrary operation to that actually disclosed in each of the cited references would be "simple common sense". Stated another way, how can it be "simple common sense" to do something contrary to the express teachings in each of the cited references. It is respectfully submitted that, in fact, the applicants of the present invention have recognized drawbacks in conventional devices such as in the cited art, and have devised the novel solution of the present invention to address such drawbacks.

The claims are directed to storing a soluble solid product within a bag whose capacity is larger than the volume of the solution to be reconstituted therein. With the use of such a large bag, there is no need for the bag to have special shapes or include special devices to ensure proper solution of the soluble solid product in a solvent because the solid product can be quickly and completely dissolved by simply vigorously shaking the bags.

- Obviously, when utilizing such a bag as claimed it is necessary to exactly measure the amount of solvent to be fed into the bag containing a measured amount of soluble solid compound. However, applicants submit that the benefits of the claimed invention overcome such a drawback as it is a simple, quick operation to introduce a desired dose volume of

solvent into a bag, while it is of great practical importance to have the possibility of completely and quickly dissolving a soluble product originally stored in the bag.

Further, what is considered in the Office Action to be common sense would actually result in a drawback in the devices of Slater, Scharf, and Beigler. Specifically, in those devices, by completely filling the bags therein, it is not necessary to measure a volume of a solvent to be injected into the bags. Instead, the bags must just be completely filled.

In contrast to the teachings in Slater, Scharf, and Beigler, the claimed invention requires an extra step of properly measuring an amount of solvent to be introduced into the bag since the bag is not completely filled with the solvent. However, the applicants believe that the benefits of the present invention outweigh that inconvenience.

In further detail, the applied art to Scharf discloses that when a solution has to be reconstituted within a bag containing a fixed, predetermined amount of sterile product in powder form, the bag must be completely filled with the solvent. That is evident from the disclosure in Scharf at column 8, line 62, column 9, line 23, column 6, lines 48-51, and the Tables in column 7 and column 8 in which it is clearly indicated that the total volume of the solution corresponds to the volume --one litre--of the bag.<sup>4</sup>

In such ways, what the Office Action indicates as "common sense" is actually directly contrary to the express disclosure in Scharf. Given that Scharf expressly discloses completely filling a bag, it is clear that it would not have been obvious to one of ordinary skill in the art to modify Scharf to not operate in that manner, particularly as no reference has been cited to even suggest not completely filling a bag.

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<sup>4</sup>At column 8, line 62, Scharf specifically indicates "[t]he bag is allowed to *fill*" (emphasis added); at column 9, lines 22-23, Scharf states "*filling* will take approximately 10 minutes. Allow bag to *fill*" (emphasis added). In the Tables in columns 7 and 8 Scharf discloses filling a one liter bag with one liter of solution.

The cited art to Beigler also discloses a bag and a method that are substantially the same as those in Scharf because the amount of solvent to be introduced into the bag completely fills the bag.<sup>5</sup>

As Beigler is similar to Scharf, clearly Beigler also does not disclose or suggest what is indicated as "common sense" in the Office Action.

Similarly to Scharf and Beigler, Slater provides teachings in which a bag is completely filled with water to prepare a solution of granulated or powder material stored therein.<sup>6</sup>

- In such ways, Slater also fails to teach or suggest what is noted in the Office Action as "common sense".

Taken from another point of view, all of Scharf, Beigler and Slater teach that in order to prepare in a bag a solution having a desired well determined concentration of a soluble solid compound, a fixed amount of which is stored within the bag, the total internal volume of such a bag must be equal to the volume of the final solution reconstituted therein. In such ways, in those devices of Scharf, Beigler, and Slater is not necessary to measure the volume of the solvent to be fed into the bag because the volume of the bag simply has to correspond to the final volume of the solution.

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- <sup>5</sup>That is also evident from Example 1 in Beigler, column 9, line 48 et. seq., which indicates that a bag of a capacity of 500 ml is "charged with 500 ml of sterile, pyrogen-free water to make the 5% aqueous dextrous solution" (column 10, lines 1-3), indicating that Beigler discloses completely filling a bag with solution.

<sup>6</sup>See Slater in the Abstract, column 3, lines 63-64, column 4, line 56, and column 5, line 6, all disclosing a bag being "filled". Slater also discloses filling a 6-8 liter bag at a rate of 1 liter per minute taking 6-8 minutes, again clearly indicating completely filling a bag in Slater (see column 5, lines 3-9)

- The problem with such an approach is that whenever a solvent is introduced into a bag to completely fill the bag, it is then difficult or even impossible to get a quick and complete dissolution of the solid material stored in the same bag.

For that reason, the bag of Scharf includes an internal mechanism within the inner side of the bag, and more particularly the bag is provided with an internal seal 14 for creating a turbulence when fluid flows into the bag 10 to ensure adequate mixing of the solute and solvent.<sup>7</sup>

Slater also explains that a bag must have a V-shape at a bottom interior to ensure that granules of solid material stored therein not only stay toward the bottom of the bag, but are also localized in a part where the water slowly flows, so that the granules stay suspended in a turbulent water flow to be dissolved.<sup>8</sup> The turbulent water flow swirls around the granules, thereby maximizing the surface area of the granules in contact with incoming water and the speed of water passing the granules.<sup>9</sup>

Moreover, since it is not possible to obtain a complete dissolution of a powdered product, Beigler teaches using a filter to remove particulate matter from a reconstituted intravenous mixture,<sup>10</sup> which obviously brings about as a consequence that the concentration of the reconstituted solution cannot have a fixed predetermined value.

In such ways, the cited art to Slater, Scharf, and Beigler teaches only utilizing bags with internal volume equal to a final volume of an injectable solution reconstituted therein.

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<sup>7</sup>See Scharf at column 1, lines 1-3, column 4, lines 43-45 and 56-60; column 2, lines 45-46, and column 6, line 30, column 10, line 14 and 48.

<sup>8</sup>Slater at Claim 1, column 4, lines 65-68, and column 5, lines 1-9.

<sup>9</sup>Slater at column 4, lines 57-62.

<sup>10</sup>Beigler at, for example, Claim 11.

As a result, such bags are further provided with devices for improving dissolution of the solid soluble materials stored therein.

Such structures in Slater, Scharf, and Beigler clearly differ from the claims as currently written.

In such ways, it is respectfully submitted that the pending claims distinguish over the applied art to Slater, Beigler, and Scharf.

As no other issues are pending in this application, it is respectfully submitted that the present application is now in a condition for allowance, and it is respectfully requested that this case be passed to issue.

Respectfully submitted,

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